K092015

510(k) Summary of Safety and Effectiveness

PERI-LOC™ Locking Bone Plates

JUL 30 2009

Submitted By:	Smith & Nephew, Inc. Orthopaedic Reconstruction and Trauma Division 1450 Brooks Road Memphis, TN 38116
Date:	July 2, 2009
Contact Person:	David Henley, Regulatory Affairs Project Manager Tel: (901) 399-6487 Fax: (901) 398-5146
Proprietary Name:	***PERI-LOC™ Periarticular Locked Plating System*** **Locking Bone Plates for Lower & Upper Extremity**
Common Name:	Bone Plates and Bone Screws
Classification Name and Reference:	21 CFR 888.3030, single/multiple component metallic bone fixation appliances and accessories - Class II
Device Product Code and Panel Code:	HRS / Orthopedics / 87

Device Description:
The subject devices are *design modifications* to **PERI-LOC™ Periarticular Locked Plating System** devices previously cleared under K033669, K051735 and K061352. Like the predicate devices listed below, the subject components include various sizes of contoured, locking bone plates made from stainless steel. PERI-LOC™ locking bone plates incorporate a screw-to-plate locking feature which forms a locked, fixed angle construct to aid in holding fracture reduction.

Design modifications include the following changes to PERI-LOC™ locking bone plates:

- Removal of *tunnels* (undercuts) from bottom-side of 3.5/4.5mm Lateral Proximal Tibia, 4.5mm Lateral Distal Femur, 2.5mm Volar Distal Radius Locking Bone Plates and 3.5mm Medial Distal Tibia Locking Bone Plates
- Removal of the 76° *chamfer* from around the top, entry point of the locking screw holes from the 4.5mm Lateral Proximal Tibia and 4.5mm Lateral Distal Femur Locking Bone Plates
- Removal of the *tab for screw hole* extension from the outer edge of the flared head section of the 3.5mm Medial Distal Tibia Locking Bone Plates.
- Removal of the *slot* (i.e. alignment slot) from the plate shaft (just below the plate head) on the 2.5mm Volar Distal Radius Locking Bone Plates and the 3.5mm Proximal Humerus Locking Bone Plates and replace the *slot* feature with a locking screw hole.

Intended Use:
The **PERI-LOC™ Periarticular Locked Plating System** can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC™ bone plates and screws are indicated for fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

Technological Characteristics:
Components comprising **PERI-LOC™ Locking Bone Plates for the Lower/Upper Extremity** are very similar to legally marketed devices listed below in that they share identical indications for use (compared to K033669, K051735 and K061352), are manufactured from identical material, and incorporate very similar technological design characteristics.

Substantial Equivalence Information:
When compared to the predicate devices listed below, substantial equivalence is based on similarities with regard to overall indications for use, material composition, and technological design characteristics.

- Smith & Nephew Locked Plating System (PERI-LOC™ Periarticular Locked Plating System) – K033669
- PERI-LOC™ Periarticular Locked Plating System for the Upper Extremity – K051735 and K061352

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Smith & Nephew, Inc.
% Mr. David Henley
Regulatory Affairs Project Manager
1450 Brooks Road
Memphis, Tennessee 38116

Re: K092015
Trade/Device Name: PERI-LOC™ Periarticular Locked Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: July 2, 2009
Received: July 6, 2009

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K092015

Device Name: PERI-LOC™ Periarticular Locked Plating System

Indications for Use:

The PERI-LOC™ Periarticular Locked Plating System can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC™ bone plates and screws are indicated for fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

Components in the PERI-LOC™ Periarticular Locked Plating System are for single use only.

Prescription Use X (Per 21 CFR 801.109) OR Over-the-Counter Use _____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092015